

HIV/HEPATITIS LABORATORY SPECIMEN RETENTION PROPOSAL

04/21/06

Approximately 950,000 serum and oral mucosal transudate (OMT) samples from routine HIV testing are stored frozen at SLI. This document outlines a strategy and plan for discarding excess specimens.

Part 1: Proposed specimen retention strategy and its rationale

HIV-NEGATIVE SERA

A collection of HIV-negative sera could be an invaluable resource in the future, when it could be used to determine past seroprevalence of new infectious agents, or seroprevalence of agents for which new serum assays have been developed. Seroprevalence of a new infectious agent in the HIV-tested population could be reasonably estimated with a sample size of 1000. For example, if IgG antibody prevalence is 50% and sample size is 1000, the 95% confidence interval would be 47-53%. If IgG prevalence is 1% and sample size is 1000, the 95% confidence interval would be 0.5-2%. Larger sample sizes could be useful for studies in which results are stratified by age or gender. However, the obstacles associated with linking HIV samples with demographic data are likely to impede such studies.

The total target serosurvey sample size will most likely be divided over a number of years. For example, the serosurvey might target 1000 sera collected between 1990 and 1999. As such, each serosurvey would likely require approximately 100 samples per year. If there is interest and funding to determine seroprevalence over time, larger sample sizes might be needed. However, it is unlikely that this larger sample size would ever exceed 1000 sera per year. Furthermore, each retained specimen is likely to be of adequate volume for multiple future tests. To establish a comfortable margin of safety in planning a specimen retention strategy, we plan to retain 5000 HIV-negative serum samples for each year of testing. This will allow us to decrease the number of stored HIV-1 negative sera from 800,000 to 90,000.

HIV-2 POSITIVE SERA AND HIV-INDETERMINATE SERA

HIV-2-positive and indeterminate sera constitute a very small number of specimens (10 HIV-2 positive specimens in last 6 years, and ~90 indeterminate specimens in the last 6 years). All of these specimens will be retained.

HIV-1 POSITIVE SERA

Positive sera can be useful for determining the seroprevalence of a second infection (eg, hepatitis C) among HIV-positive individuals. As HIV group- and subtype-specific serum assays are developed, a bank of HIV-antibody positive specimens can also be useful in determining past prevalence of a specific HIV group/type. HIV-1 positive sera are also often used in the validation of new tests. No more than 1000 specimens (divided over several years) would be likely to be needed for each study, and each validation study usually requires no more than 100 positive specimens. However, because HIV-1-positive

sera constitute a relatively small proportion of the total number of samples currently stored at SLI, we will plan to retain all HIV-1 positive sera for the present.

OMT SPECIMENS

Testing data collected to date suggest that IgG can be reliably detected in OMT specimens up to at least 6 months after freezing. Usefulness of frozen OMT specimens stored for greater than 6 months has not been established. For the time being, we plan to retain 5000 negative OMT specimens per year of testing, and all positive OMT specimens. This would decrease the number of stored OMT specimens from 90,000 to 40,000. If further study demonstrates a limited shelf life for these stored specimens, they can be discarded after the shelf life has been exceeded.

Part 2: Procedure for destruction of selected stored specimens, by year of initial testing

1984-1987: Only confirmatory testing was done, on fewer than 2000 specimens per year. Retain all of these specimens.

1988: Only ~2000 specimens total. Retain all.

1989-2005: Samples are stored in boxes of 100. Retain the first of every 4 –17 sequential boxes as appropriate to reach a total of 50 boxes of 100 specimens for each testing year. Discard the remainder. Scan the barcode for each tube prior to discard, to identify final test result for that specimen. When positive or indeterminate samples are identified, retain these specimens in a separate box of positive/indeterminate samples. For retained specimens, record VL numbers (or ranges of numbers), test result, and the freezer number and rack number to which they are returned. For discarded specimens, record VL number (or range of numbers) and date of destruction.

2006 and beyond: All samples should be retained for a minimum of 6 months following testing. In addition, specimens should not be discarded until the total number of specimens tested during the calendar year has been established (to determine the number of boxes to be discarded in order to retain 5000 negative specimens). Specifically, specimens tested in 2006 should not be discarded until January 2007, and specimens tested during the last 6 months of 2006 should not be discarded until July 2007.

YEAR	LOCATION (SLI room #'s)	SERUM SAMPLES	POS SERUM TO SAVE	NEG SERUM SAMPLES	NEG SERUM TO SAVE	1 in x boxes to be saved	OMT SAMPLES	POS OMT TO SAVE	NEG OMT SAMPLES	NEG OMT TO SAVE	1 in x boxes to be saved
1984*	547										
1985*	797										
1986*	547										
1987*	547										
1988	347, 797	2,096	159	1937	1,937	all	0	0	0	0	0
1989	347, 747, 797, 847	23,265	1,297	21968	5,000	4	0	0	0	0	0
1990	547, 847	29,520	1,581	27939	5,000	6	0	0	0	0	0
1991	347, 797, 847	42,122	2,058	40064	5,000	8	0	0	0	0	0
1992	347, 747, 797, 847	51,172	1,747	49425	5,000	10	0	0	0	0	0
1993	347, 747, 797	65,025	2,925	62100	5,000	12	0	0	0	0	0
1994	747	64,654	2,662	61992	5,000	12	0	0	0	0	0
1995	747	82,296	3,184	79112	5,000	16	0	0	0	0	0
1996	747	86,743	3,275	83468	5,000	17	34	3	31	31	all
1997	747	80,057	3,473	76584	5,000	15	508	27	481	481	all
1998	747	54,797	1,342	53455	5,000	11	1934	89	1,845	1,845	all
1999	747, 797, 847	63,302	2,349	60953	5,000	12	5573	85	5,488	5000	all
2000	747, 797	54,197	1,640	52557	5,000	11	9426	95	9,331	5000	2
2001	797	48,384	1,187	47197	5,000	9	14212	137	14,075	5000	3
2002	797	33,806	580	33226	5,000	7	17635	266	17,369	5000	3
2003	797	26,780	353	26427	5,000	5	16023	155	15,868	5000	3
2004		22746	382	22364	5,000	4	13489	121	13,368	5000	3
2005		19953	298	19655	5,000	4	11811	103	11,708	5000	2
TOTAL		850,915	30,492	820,423	86,937		90,645	1,081	89,564	37,357	

* Only HIV confirmatory testing performed. Specimens for these years are archived with serology and number under 2,000/year.

TOTAL RETAINED SPECIMENS FROM 1988-2005 INCLUSIVE:	941,560
SPECIMENS TO BE RETAINED AS PER 03/2006 PROPOSAL:	155,867

# SPECIMENS TO BE DISCARDED:	785,693
# ROLLING RACKS TO BE EMPTIED:	79